

1. Restriction of Claims 1 to 54 as drawn to different inventions.

The application was subject to a four (4) way restriction requirement as being drawn to the following inventions:

Group I : drawn to drug composition Claims 1 to 14.

Group II : drawn to gelled compositions Claims 15 to 21.

Group III: drawn to method of treatment Claims 22 to 24.

Group IV : drawn to method of making the drug composition of Group I covered by Claims 35 to 51.

ELECTION

The claims of Group I, namely, Claims 1 to 14 were elected with traverse.

TRAVERSE

While the Examiner has asserted that the various claims of the inventions are independent and distinct, namely, the inventions of Groups I and II; Groups I and III; Groups II and III; Groups I and IV; Groups II and IV; and Groups III and IV; the restriction requirement is improper in not allowing the Applicant to combine either the claims of Group I with the claims of Group III or the claims of Group IV. The claimed subject matter of these Groups are not independent, but represent overlapping inventions that would involve the same prior art search and examination. Note that the treatment of claims of Group III use the same drug composition covered by the Group I claims. Also, the method of making claims of Group IV specifically make the composition covered by the Group I claims. Accordingly, Applicants request reconsideration and

withdrawal of the restriction requirement and an examination of the claims covered specifically by Groups I and III.

The non-elected claims will be withdrawn upon a determination of allowable subject matter by the Examiner.

2. Rejection of Claims 13 and 14 under 35 U.S.C. § 112, second paragraph.

Claims 13 and 14 were rejected on the basis that the weight percents of the components recited were not recited. Claims 13 and 14 have been amended to recite that their respective weight percentages are based upon the weight of the entire composition which is consistent with the disclosure. Accordingly, withdrawal of this rejection is respectfully requested.

3. Rejection of Claims 1 to 14 under 35 U.S.C. § 112, first paragraph.

Claims 1 to 14 stand rejected under 35 U.S.C. § 112 for failing to be enabling for the specific polymers disclosed and ratio of the polymers employed in the inventive subject matter. This rejection has been obviated by the amendment to Claim 1 which incorporates the specific negatively charged polymers and nonionic polymers into Claim 1 along with a recitation of the polymers that are useable in the present invention. Accordingly, withdrawal of this rejection is respectfully requested.

4. Rejection of Claims 1-5, 8-10, 12 and 13 under 35 U.S.C. § 102(e) as being anticipated by Lindbad et al.

As the basis for the rejection, the Examiner contends that Lindbad et al. disclose compositions for use in surgical operations using solutions of dextran and hyaluronic acid and that such solutions anticipate the original claims.

Applicants respectfully traverse this rejection. The Lindbad et al. reference does not teach or suggest Applicants' inventive subject matter as a whole as recited in the amended claims.

To constitute anticipation under 35 U.S.C. § 102, all material elements of a claim must be disclosed in one prior art source. In re Marshall, 577 F.2d 301, 198 USPQ 344 (CCPA 1978); In re Kalm, 378 F.2d 959, 154 USPQ 10 (CCPA 1967). A claimed combination is not obvious over a reference if a material claim limitation is absent from the reference. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Lindbad et al. does not anticipate the amended claims. At best, Lindbad et al. disclose a composition for use in surgical operations to prevent adhesions between tissue surfaces wherein the composition is an aqueous solution containing dextran in amounts of 7 to 20% and hyaluronic acid in amounts of 0.5 to 6%. Furthermore, the molecular weight of the hyaluronic acid is within the range of 500,000 to 6,000,000.

In complete contrast to the referenced subject matter, it should be initially noted that Applicants inventive subject matter requires the formation of a long acting drug composition that is sterilized and purified. Such limitations are not taught by Lindbad et al.

In addition, Applicants' claims require the essential presence of two specific polymer ingredients, namely negatively charge polymers, such as polysulfated glucosaglycans, glycosaminoglycans, mucopolysaccharides as well as hyaluronic acid salts, and nonionic polymers such as carboxymethyl cellulose sodium, hydroxyethyl-cellulose and hydroxypropylcellulose. The Lindbad et al. dextran material is a carbohydrate and not one of the essential polymers of Applicants' inventive subject matter.

Furthermore, the Lindbad et al. use of 7 to 20% dextran and 0.5 to 6% hyaluronic acid fails to teach or suggest Applicants' essential use of molar ratios of the negatively charged polymers to nonionic polymers of 1:0.5 to 2. Such ratios are essential in Applicants' composition so that a stable solution and suspension can be prepared and remain effective as a long acting drug composition.

Accordingly, withdrawal of the Lindbad et al. reference and allowance of the claims is respectfully requested.

5. Rejection of claims 6 and 11 under 35 U.S.C. § 103 as unpatentable over Lindbad et al.

To avoid repetition, Applicants' hereby incorporate by reference the remarks presented above with regard to the teachings and deficiencies of the Lindbad et al. reference.

The U.S. Supreme Court in *Graham v. John Deere Co.*, 148 USPQ 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims

at issue; (3) resolving the level of ordinary skill in the art.

Applicants' claims as presently amended are directed to independent and distinct subject matter from that disclosed by Lindbad et al. The reference does not teach or suggest a combination of negatively charged polymers with nonionic polymers let alone their critical ratio to achieve a long acting drug composition. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection.

It is readily apparent that there is no disclosure of facts in the prior art which support a legal conclusion that the claimed invention was obvious at the time it was made. It is a well settled principle that prior patents are references only for what they clearly disclose or suggest and that it is not proper use of a patent as a reference to modify its structure to one which the reference does not suggest.

It is readily apparent from the reference relied upon that the technology disclosed in our application is totally unrelated to that which is disclosed by this reference.

The provisions of Section 103 must be followed realistically to develop the factual background against which the Section 103 determination must be made. All of the facts must be considered and it is not realistic within the framework of Section 103 to pick and choose from any one reference only so much as will support a given position to the exclusion of other parts necessary for the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. Accordingly, withdrawal of the

reference and an allowance of the claims is respectfully requested.

CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the rejection of the claims and allow all pending claims presented herein for reconsideration. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if he has any questions or comments.

Respectfully submitted

**NATH & ASSOCIATES**

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